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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/076,618	05/12/98	PAPAHADJIOPOULOS	D 02307E-07142

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EXAMINER

KETTER, J

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

06/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Response Due

7-24-99 ms

— SEE ATTACHED —

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Office Action Summary

Application No.

09/076,618

Applicant(s)

Papahadjopoulos et al.

Examiner

J. KETTER

Group Art Unit

1636

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-70 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-70 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-47, drawn to complexes comprising an organic polycation, and to methods of making same, and to methods of transfecting using same, classified in class 435, subclass 440+.
- II. Claims 48-54, drawn to a pharmaceutical composition comprising a polycation, classified in class 536, subclass 23.1+.
- III. Claims 55-58, drawn to kits comprising a liposome, a nucleic acid, and a hydrophilic polymer, classified in class 424, subclass 450.
- IV. Claims 59-80, drawn to methods of conjugating a protein molecule to a lipidic microparticle, and to conjugated lipidic microparticles, classified in class 530, subclass 300+ and 350+.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I, Group II, Group III and Group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case the products claimed in the different inventions are drawn to chemically distinct entities, capable of supporting separate patents. The complexes of Group I are more narrowly claimed than those of group II with respect to the polycation, and those of Group II are limited to pharmaceuticals. The components of the kits of Group III have not been combined to form complexes, but are merely collections of those three components. As such, they are chemically

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distinct from complexes. The conjugated complexes of Group IV comprise protein/peptide moieties not present in Groups I-III, and are made by a different process.

Furthermore, the methods in Group I are drawn to making complexes comprising organic polycations, and methods of using said complexes for transfection. The methods of Group IV, however, are drawn to methods of modifying an existing lipidic microparticles by conjugation to a protein. The respective methods of Groups I and IV employ different process steps to a different purpose or effect.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Certain papers related to this application may be submitted to Art Unit 1805 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR §

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1.6(d)). The Art Unit 1805 Fax number is (703) 308-0294. NOTE: If Applicant *does* submit a paper by fax to this number, the examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the examiner, with such faxed papers being handled in the manner of mailed responses.

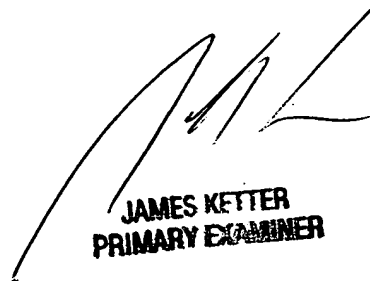
Applicants are encouraged to use the latter two fax numbers unless immediate action by the examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner can normally be reached on Monday-Thursday from 8:00 AM-5:30 PM, and on alternate Fridays.

If attempts to reach the Examiner are unsuccessful, the Examiner's supervisor, George Elliott, can be contacted at (703) 308-4003.

James Ketter

June 16, 1999



JAMES KETTER
PRIMARY EXAMINER